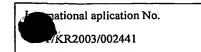
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference		SeeNotificatio	nofTransmittalofInternationalI	Preliminary			
PCA31168/HMY	FOR FURTHER ACTION Examination		Report (Form PCT/IPEA/416)				
International application No.	International filing date(day/mo		Priority date (day/month/year 13 NOVEMBER 2002 (13.1				
PCT/KR2003/002441	13 NOVEMBER 2003 (13 1(0 V ENIBER 2002 (13))				
International Patent Classification (IPC) IPC7 A61K 9/14) of flational classification and h						
HANMI PHARM. CO., LTD.							
 This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 							
2. This REPORT consists of a total of3 sheets, including this cover sheet.							
This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).							
These annexes consist of a total ofsheets.							
3. This report contains indications	relating to the following items:						
I X Basis of the repor	ţ						
II Priority							
1 _1	at of opinion with regard to novel	ty, inventive step	and industrial applicability				
IV Lack of unity of i	ent under Article 35(2) with rega	erd to novelty, inve	entive step or industrial applica	bility;			
citations and expl	anations supporting such stateme	ent					
· · ·							
VII Certain defects in	the international application						
VIII Certain observati	ons on the international application	on		,			
Date of submission of the demand	Da	ate of completion	of this report				
Date of submission of the domains		•		•			
03 JUNE 2004 (03.06.2004)		27 DECEM	IBER 2004 (27.12.2004)				
Name and mailing address of the IPEA/KR		uthorized officer		Manes			
Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea		Yoon, Kyung	Ae				
Facsimile No. 82-42-472-7140		elephone No. 82-	42-481-5605	AND AND TO S			



I.	Basis	of the report						
1.	With	egard to the elements of the international application:*						
	\mathbf{x}	he international application as originally filed						
		the description:						
		pages	, as originally filed , filed with the demand					
		pages, filed with the le	etter of					
		the claims:						
	pages, as origina pages, as amended (together with any statment) under							
		pages, as amended	, filed with the demand					
		pages, filed with the le	etter of					
		the drawings:						
		pages	, as originally filed					
		pages filed with the let	tter of					
		the sequence listing part of the description:						
		pagespages						
		pages, filed with the let	tter of					
2.	With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language English which is the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). The language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).							
3	 With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international application was carried out on the basis of the sequence listing: contained inthe international application in written form. 							
		filed together with the international application in computer readable form	.					
		furnished subsequently to this Authority in written form.						
		furnished subsequently to this Authority in computer readable form						
		The statement that the subsequently furnished written sequence listin international applicationas as filed has been furinshed.	ng does not go beyond the disc losure in the					
		The statement that the information recorded in computer readable form been furnished.	is identical to the written sequence listing has					
4.		The amendments have resulted in the cancellation of:						
		the description, pages	•					
		the claims, Nos.						
5.		the drawings, sheets						
		This report has been established as if (some of) the amendments had no go beyond the disclosure as filed, as indicated in the Supplemental Box(l						
*	in th	acement sheets which have been furnished to the receiving Office in response is opinion as "originally filed." and are not annexed to this report since th 70.17).						
	** Any	replacement sheet containing such amendments must be referred to under it	tem I and annexed to this report.					

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

7			
Statement			
Novelty (N)	Claims	1-13	YES
	Claims	none	NO
Inventive step (IS)	Claims	1-13	YES
• , ,	Claims	none	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims	none	NO
	Inventive step (IS)	Novelty (N) Claims Claims Inventive step (IS) Claims Claims Claims Claims	Novelty (N) Claims Claims Inventive step (IS) Claims Claims Claims Claims 1-13 none Industrial applicability (IA) Claims 1-13

2. Citations and explanations (Rule 70.7)

The present invention relates to a method for the preparation of paclitaxel solid dispersion by using the supercritical fluid process and paclitaxel solid dispersion prepared thereby.

The following documents have been considered for the purpose of this report:

 $D1 = W0 \ 01-62753 \ A1 \ (30. \ 08. \ 2001)$

D2 = W0 02-30466 A2 (18. 04. 2002)

D3 = W0 00-50007 A1 (31. 08. 2000)

D4 = US 6338859 B1 (15. 01. 2002)

1. Novelty and Inventive Step

- D1 discloses methods for isolating taxol using supercritical fluid and a cosolvent extraction step from source materials.
- D2 discloses a pharmaceutical composition comprising paclitaxel and a solubilizing compound selected from the group consisting of hydrotropic agent monomers, hydrotropic polymers, and hydrotropic hydrogels.
- D3 discloses a triglyceride-free pharmaceutical composition comprising a hydrophobic therapeutic agent a carrier (a mixture of a hydrophilic surfactant and a hydrophobic surfactant)
- D4 discloses a micelle-foaming composition comprising a therapeutic agent and a hydrophobic core surrounded by a hydrophilic shell (PVP).

However, none of the documents D1-D4 disclose a highly uniform nano-scale paclitaxel solid dispersion prepared by using the supercritical fluid process. Accordingly, the present invention is not considered to be easily invented from the invention disclosed in D1-D4 by a person skilled in the art. Therefore, the novelty and inventive step of the present invention can be acknowledged, and claims 1 to 13 meet the requirements of PCT Article 33(2) and 33(3).

2. Industrial Applicability